

112TH CONGRESS
2D SESSION

H. R. 3988

To amend the Federal Food, Drug, and Cosmetic Act to establish user-fee programs for generic drugs and biosimilars.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 8, 2012

Mr. MURPHY of Pennsylvania (for himself, Mr. PALLONE, Mr. PITTS, and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish user-fee programs for generic drugs and biosimilars.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 This Act may be cited as the “Generic Drug and Bio-
5 similar User Fee Act of 2012”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Table of contents.

TITLE I—FEES RELATING TO GENERIC DRUGS

Sec. 101. Short title; references in title; findings.

- Sec. 102. Authority to assess and use human generic drug fees.
 Sec. 103. Reauthorization; reporting requirements.
 Sec. 104. Sunset dates.
 Sec. 105. Effective date.
 Sec. 106. Amendment with respect to misbranding.
 Sec. 107. Electronic submission of applications.
 Sec. 108. Streamlined hiring authority of the Food and Drug Administration to support activities related to human generic drugs.

TITLE II—FEES RELATING TO BIOSIMILAR BIOLOGICAL
 PRODUCTS

- Sec. 201. Short title; references in title; finding.
 Sec. 202. Fees relating to biosimilar biological products.
 Sec. 203. Reauthorization; reporting requirements.
 Sec. 204. Sunset dates.
 Sec. 205. Effective date.
 Sec. 206. Savings clause.
 Sec. 207. Technical amendment; conforming amendment.

1 **TITLE I—FEES RELATING TO**
 2 **GENERIC DRUGS**

3 **SEC. 101. SHORT TITLE; REFERENCES IN TITLE; FINDINGS.**

4 (a) **SHORT TITLE.**—This title may be cited as the
 5 “Generic Drug User Fee Amendments of 2012”.

6 (b) **REFERENCES IN ACT.**—Except as otherwise spec-
 7 ified, amendments made by this title to a section or other
 8 provision of law are amendments to such section or other
 9 provision of the Federal Food, Drug, and Cosmetic Act
 10 (21 U.S.C. 301 et seq.).

11 (c) **FINDINGS.**—The Congress finds that the fees au-
 12 thorized by the amendments made in this title will be dedi-
 13 cated, as set forth in the goals identified in the letters
 14 from the Secretary of Health and Human Services to the
 15 Chairman of the Committee on Health, Education, Labor,
 16 and Pensions of the Senate and the Chairman of the Com-
 17 mittee on Energy and Commerce of the House of Rep-

1 representatives, as set forth in the Congressional Record.
2 These fees are intended to help the Food and Drug Ad-
3 ministration ensure that participants in the United States
4 generic drug system comply with United States quality
5 standards, and to increase the likelihood that American
6 consumers have timely access to low-cost, high-quality ge-
7 neric drugs. A comprehensive human generic drug user fee
8 program, to be supplemental to traditional appropriated
9 funding, should be focused on three key aims:

10 (1) SAFETY.—Ensure that industry partici-
11 pants, foreign or domestic, who participate in the
12 United States generic drug system are held to con-
13 sistent high-quality standards and are inspected bi-
14 ennially, using a risk-based approach, with foreign
15 and domestic parity.

16 (2) ACCESS.—Expedite the availability of low-
17 cost, high-quality generic drugs by bringing greater
18 predictability to the review times for abbreviated
19 new drug applications, amendments, and supple-
20 ments, increasing predictability and timeliness in the
21 review process.

22 (3) TRANSPARENCY.—Enhance the Food and
23 Drug Administration’s ability to protect Americans
24 in the complex global supply environment by requir-
25 ing the identification of facilities involved in the

1 manufacture of generic drugs and associated active
2 pharmaceutical ingredients, and improving the Food
3 and Drug Administration’s communications and
4 feedback with industry in order to expedite product
5 access.

6 **SEC. 102. AUTHORITY TO ASSESS AND USE HUMAN GE-**
7 **NERIC DRUG FEES.**

8 Subchapter C of chapter VII (21 U.S.C. 379f et seq.)
9 is amended by adding at the end the following:

10 **“PART 7—FEES RELATING TO GENERIC DRUGS**

11 **“SEC. 744A. DEFINITIONS.**

12 “For purposes of this part:

13 “(1) The term ‘abbreviated new drug applica-
14 tion’—

15 “(A) means an application submitted
16 under section 505(j), an abbreviated application
17 submitted under section 507 (as in effect on the
18 day before the date of enactment of the Food
19 and Drug Administration Modernization Act of
20 1997), or an abbreviated new drug application
21 submitted pursuant to regulations in effect
22 prior to the implementation of the Drug Price
23 Competition and Patent Term Restoration Act
24 of 1984; and

1 “(B) does not include an application for a
2 positron emission tomography drug.

3 “(2) The term ‘active pharmaceutical ingre-
4 dient’ means—

5 “(A) a substance, or a mixture when the
6 substance is unstable or cannot be transported
7 on its own, intended—

8 “(i) to be used as a component of a
9 drug; and

10 “(ii) to furnish pharmacological activ-
11 ity or other direct effect in the diagnosis,
12 cure, mitigation, treatment, or prevention
13 of disease, or to affect the structure or any
14 function of the human body; or

15 “(B) a substance intended for final crys-
16 tallization, purification, or salt formation, or
17 any combination of those activities, to become a
18 substance or mixture described in subparagraph
19 (A).

20 “(3) The term ‘adjustment factor’ means a fac-
21 tor applicable to a fiscal year that is the Consumer
22 Price Index for all urban consumers (all items;
23 United States city average) for October of the pre-
24 ceding fiscal year divided by such Index for October
25 2011.

1 “(4) The term ‘affiliate’ means a business enti-
2 ty that has a relationship with a second business en-
3 tity if, directly or indirectly—

4 “(A) one business entity controls, or has
5 the power to control, the other business entity;
6 or

7 “(B) a third party controls, or has power
8 to control, both of the business entities.

9 “(5)(A) The term ‘facility’—

10 “(i) means a business or other entity—

11 “(I) under one management, either di-
12 rect or indirect; and

13 “(II) at one geographic location or ad-
14 dress engaged in manufacturing or proc-
15 essing an active pharmaceutical ingredient
16 or a finished dosage form; and

17 “(ii) does not include a business or other
18 entity whose only manufacturing or processing
19 activities are one or more of the following: re-
20 packaging, relabeling, or testing.

21 “(B) For purposes of subparagraph (A), sepa-
22 rate buildings within close proximity are considered
23 to be at one geographic location or address if the ac-
24 tivities in them are—

1 “(i) closely related to the same business
2 enterprise;

3 “(ii) under the supervision of the same
4 local management; and

5 “(iii) capable of being inspected by the
6 Food and Drug Administration during a single
7 inspection.

8 “(C) If a business or other entity would meet
9 the definition of a facility under this paragraph but
10 for being under multiple management, the business
11 or other entity is deemed to constitute multiple fa-
12 cilities, one per management entity, for purposes of
13 this paragraph.

14 “(6) The term ‘finished dosage form’ means—

15 “(A) a drug product in the form in which
16 it will be administered to a patient, such as a
17 tablet, capsule, solution, or topical application;

18 “(B) a drug product in a form in which re-
19 constitution is necessary prior to administration
20 to a patient, such as oral suspensions or
21 lyophilized powders; or

22 “(C) any combination of an active pharma-
23 ceutical ingredient with another component of a
24 drug product for purposes of production of a

1 drug product described in subparagraph (A) or
2 (B).

3 “(7) The term ‘generic drug submission’ means
4 an abbreviated new drug application, an amendment
5 to an abbreviated new drug application, or a prior
6 approval supplement to an abbreviated new drug ap-
7 plication.

8 “(8) The term ‘human generic drug activities’
9 means the following activities of the Secretary asso-
10 ciated with generic drugs and inspection of facilities
11 associated with generic drugs:

12 “(A) The activities necessary for the re-
13 view of generic drug submissions, including re-
14 view of drug master files referenced in such
15 submissions.

16 “(B) The issuance of—

17 “(i) approval letters which approve
18 abbreviated new drug applications or sup-
19 plements to such applications; or

20 “(ii) complete response letters which
21 set forth in detail the specific deficiencies
22 in such applications and, where appro-
23 priate, the actions necessary to place such
24 applications in condition for approval.

1 “(C) The issuance of letters related to
2 Type II active pharmaceutical drug master files
3 which—

4 “(i) set forth in detail the specific de-
5 ficiencies in such submissions, and where
6 appropriate, the actions necessary to re-
7 solve those deficiencies; or

8 “(ii) document that no deficiencies
9 need to be addressed.

10 “(D) Inspections related to generic drugs.

11 “(E) Monitoring of research conducted in
12 connection with the review of generic drug sub-
13 missions and drug master files.

14 “(F) Postmarket safety activities with re-
15 spect to drugs approved under abbreviated new
16 drug applications or supplements, including the
17 following activities:

18 “(i) Collecting, developing, and re-
19 viewing safety information on approved
20 drugs, including adverse event reports.

21 “(ii) Developing and using improved
22 adverse-event data-collection systems, in-
23 cluding information technology systems.

24 “(iii) Developing and using improved
25 analytical tools to assess potential safety

1 problems, including access to external data
2 bases.

3 “(iv) Implementing and enforcing sec-
4 tion 505(o) (relating to postapproval stud-
5 ies and clinical trials and labeling changes)
6 and section 505(p) (relating to risk evalua-
7 tion and mitigation strategies) insofar as
8 those activities relate to abbreviated new
9 drug applications.

10 “(v) Carrying out section 505(k)(5)
11 (relating to adverse event reports and
12 postmarket safety activities).

13 “(G) Regulatory science activities related
14 to generic drugs.

15 “(9) The term ‘positron emission tomography
16 drug’ has the meaning given to the term ‘com-
17 pounded positron emission tomography drug’ in sec-
18 tion 201(ii), except that paragraph (1)(B) of such
19 section shall not apply.

20 “(10) The term ‘prior approval supplement’
21 means a request to the Secretary to approve a
22 change in the drug substance, drug product, produc-
23 tion process, quality controls, equipment, or facilities
24 covered by an approved abbreviated new drug appli-
25 cation when that change has a substantial potential

1 to have an adverse effect on the identity, strength,
2 quality, purity, or potency of the drug product as
3 these factors may relate to the safety or effective-
4 ness of the drug product.

5 “(11) The term ‘resources allocated for human
6 generic drug activities’ means the expenses for—

7 “(A) officers and employees of the Food
8 and Drug Administration, contractors of the
9 Food and Drug Administration, advisory com-
10 mittees, and costs related to such officers and
11 employees and to contracts with such contrac-
12 tors;

13 “(B) management of information, and the
14 acquisition, maintenance, and repair of com-
15 puter resources;

16 “(C) leasing, maintenance, renovation, and
17 repair of facilities and acquisition, maintenance,
18 and repair of fixtures, furniture, scientific
19 equipment, and other necessary materials and
20 supplies; and

21 “(D) collecting fees under subsection (a)
22 and accounting for resources allocated for the
23 review of abbreviated new drug applications and
24 supplements and inspection related to generic
25 drugs.

1 fee shall be calculated by dividing \$50,000,000
2 by the total number of abbreviated new drug
3 applications pending on October 1, 2012, that
4 have not received a tentative approval as of that
5 date.

6 “(C) NOTICE.—Not later than October 31,
7 2012, the Secretary shall cause to be published
8 in the Federal Register a notice announcing the
9 amount of the fee required by subparagraph
10 (A).

11 “(D) FEE DUE DATE.—The fee required
12 by subparagraph (A) shall be due no later than
13 30 calendar days after the date of the publica-
14 tion of the notice specified in subparagraph (C).

15 “(2) DRUG MASTER FILE FEE.—

16 “(A) IN GENERAL.—Each person that
17 owns a Type II active pharmaceutical ingre-
18 dient drug master file that is referenced on or
19 after October 1, 2012, in a generic drug sub-
20 mission by any initial letter of authorization
21 shall be subject to a drug master file fee.

22 “(B) ONE-TIME PAYMENT.—If a person
23 has paid a drug master file fee for a Type II
24 active pharmaceutical ingredient drug master
25 file, the person shall not be required to pay a

1 subsequent drug master file fee when that Type
2 II active pharmaceutical ingredient drug master
3 file is subsequently referenced in generic drug
4 submissions.

5 “(C) NOTICE.—

6 “(i) FISCAL YEAR 2013.—Not later
7 than October 31, 2012, the Secretary shall
8 cause to be published in the Federal Reg-
9 ister a notice announcing the amount of
10 the drug master file fee for fiscal year
11 2013.

12 “(ii) FISCAL YEAR 2014 THROUGH
13 2017.—Not later than 60 days before the
14 start of each of fiscal years 2014 through
15 2017, the Secretary shall cause to be pub-
16 lished in the Federal Register the amount
17 of the drug master file fee established by
18 this paragraph for such fiscal year.

19 “(D) AVAILABILITY FOR REFERENCE.—

20 “(i) IN GENERAL.—Subject to sub-
21 section (g)(2)(C), for a generic drug sub-
22 mission to reference a Type II active phar-
23 maceutical ingredient drug master file, the
24 drug master file must be deemed available
25 for reference by the Secretary.

1 “(ii) CONDITIONS.—A drug master
2 file shall be deemed available for reference
3 by the Secretary if—

4 “(I) the person that owns a Type
5 II active pharmaceutical ingredient
6 drug master file has paid the fee re-
7 quired under subparagraph (A) within
8 20 calendar days after the applicable
9 due date under subparagraph (E);
10 and

11 “(II) the drug master file has not
12 failed an initial completeness assess-
13 ment by the Secretary, in accordance
14 with criteria to be published by the
15 Secretary.

16 “(iii) LIST.—The Secretary shall
17 make available on the public Internet Web
18 site of the Food and Drug Administration
19 a list of the drug master file numbers that
20 correspond to drug master files that have
21 successfully undergone an initial complete-
22 ness assessment, in accordance with cri-
23 teria to be published by the Secretary, and
24 are available for reference.

25 “(E) FEE DUE DATE.—

1 “(i) IN GENERAL.—Subject to clauses
2 (ii), a drug master file fee shall be due no
3 later than the date on which the first ge-
4 neric drug submission is submitted that
5 references the associated Type II active
6 pharmaceutical ingredient drug master file.

7 “(ii) LIMITATION.—No fee shall be
8 due under subparagraph (A) for a fiscal
9 year until the later of—

10 “(I) 30 calendar days after publi-
11 cation of the notice provided for in
12 clause (i) or (ii) of subparagraph (C),
13 as applicable; or

14 “(II) 30 calendar days after the
15 date of enactment of an appropria-
16 tions Act providing for the collection
17 and obligation of fees under this sec-
18 tion

19 “(3) ABBREVIATED NEW DRUG APPLICATION
20 AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—

21 “(A) IN GENERAL.—Each applicant that
22 submits, on or after October 1, 2012, an abbrevi-
23 ated new drug application or a prior approval
24 supplement to an abbreviated new drug applica-
25 tion shall be subject to a fee for each such sub-

1 mission in the amount established under sub-
2 section (d).

3 “(B) NOTICE.—

4 “(i) FISCAL YEAR 2013.—Not later
5 than October 31, 2012, the Secretary shall
6 cause to be published in the Federal Reg-
7 ister a notice announcing the amount of
8 the fees under subparagraph (A) for fiscal
9 year 2013.

10 “(ii) FISCAL YEARS 2014 THROUGH
11 2017.—Not later than 60 days before the
12 start of each of fiscal years 2014 through
13 2017, the Secretary shall cause to be pub-
14 lished in the Federal Register the amount
15 of the fees under subparagraph (A) for
16 such fiscal year.

17 “(C) FEE DUE DATE.—

18 “(i) IN GENERAL.—Except as pro-
19 vided in clause (ii), the fees required by
20 subparagraphs (A) and (F) shall be due no
21 later than the date of submission of the
22 abbreviated new drug application or prior
23 approval supplement for which such fee ap-
24 plies.

1 “(ii) SPECIAL RULE FOR 2013.—For
2 fiscal year 2013, such fees shall be due on
3 the later of—

4 “(I) the date on which the fee is
5 due under clause (i);

6 “(II) 30 calendar days after pub-
7 lication of the notice referred to in
8 subparagraph (B)(i); or

9 “(III) if an appropriations Act is
10 not enacted providing for the collec-
11 tion and obligation of fees under this
12 section by the date of submission of
13 the application or prior approval sup-
14 plement for which the fees under sub-
15 paragraphs (A) and (F) apply, 30 cal-
16 endar days after the date that such an
17 appropriations Act is enacted.

18 “(D) REFUND OF FEE IF ABBREVIATED
19 NEW DRUG APPLICATION IS NOT CONSIDERED
20 TO HAVE BEEN RECEIVED.—The Secretary
21 shall refund 75 percent of the fee paid under
22 subparagraph (A) for any abbreviated new drug
23 application or prior approval supplement to an
24 abbreviated new drug application that the Sec-
25 retary considers not to have been received with-

1 in the meaning of section 505(j)(5)(A) for a
2 cause other than failure to pay fees.

3 “(E) FEE FOR AN APPLICATION THE SEC-
4 RETARY CONSIDERS NOT TO HAVE BEEN RE-
5 CEIVED, OR THAT HAS BEEN WITHDRAWN.—An
6 abbreviated new drug application or prior ap-
7 proval supplement that was submitted on or
8 after October 1, 2012, and that the Secretary
9 considers not to have been received, or that has
10 been withdrawn, shall, upon resubmission of the
11 application or a subsequent new submission fol-
12 lowing the applicant’s withdrawal of the appli-
13 cation, be subject to a full fee under subpara-
14 graph (A).

15 “(F) ADDITIONAL FEE FOR ACTIVE PHAR-
16 MACEUTICAL INGREDIENT INFORMATION NOT
17 INCLUDED BY REFERENCE TO TYPE II ACTIVE
18 PHARMACEUTICAL INGREDIENT DRUG MASTER
19 FILE.—An applicant that submits a generic
20 drug submission on or after October 1, 2012,
21 shall pay a fee, in the amount determined under
22 subsection (d)(3), in addition to the fee re-
23 quired under subparagraph (A), if—

24 “(i) such submission contains infor-
25 mation concerning the manufacture of an

1 active pharmaceutical ingredient at a facil-
2 ity by means other than reference by a let-
3 ter of authorization to a Type II active
4 pharmaceutical drug master file; and

5 “(ii) a fee in the amount equal to the
6 drug master file fee established in para-
7 graph (2) has not been previously paid
8 with respect to such information.

9 “(4) GENERIC DRUG FACILITY FEE AND ACTIVE
10 PHARMACEUTICAL INGREDIENT FACILITY FEE.—

11 “(A) IN GENERAL.—Facilities identified,
12 or intended to be identified, in at least one ge-
13 neric drug submission that is pending or ap-
14 proved to produce a finished dosage form of a
15 human generic drug or an active pharma-
16 ceutical ingredient contained in a human ge-
17 neric drug shall be subject to fees as follows:

18 “(i) GENERIC DRUG FACILITY.—Each
19 person that owns a facility which is identi-
20 fied or intended to be identified in at least
21 one generic drug submission that is pend-
22 ing or approved to produce one or more
23 finished dosage forms of a human generic
24 drug shall be assessed an annual fee for
25 each such facility.

1 “(ii) ACTIVE PHARMACEUTICAL IN-
2 GREDIENT FACILITY.—Each person that
3 owns a facility which produces, or which is
4 pending review to produce, one or more ac-
5 tive pharmaceutical ingredients identified,
6 or intended to be identified, in at least one
7 generic drug submission that is pending or
8 approved or in a Type II active pharma-
9 ceutical ingredient drug master file ref-
10 erenced in such a generic drug submission,
11 shall be assessed an annual fee for each
12 such facility.

13 “(iii) FACILITIES PRODUCING BOTH
14 ACTIVE PHARMACEUTICAL INGREDIENTS
15 AND FINISHED DOSAGE FORMS.—Each
16 person that owns a facility identified, or
17 intended to be identified, in at least one
18 generic drug submission that is pending or
19 approved to produce both one or more fin-
20 ished dosage forms subject to clause (i)
21 and one or more active pharmaceutical in-
22 gredients subject to clause (ii) shall be
23 subject to fees under both such clauses for
24 that facility.

1 “(B) AMOUNT.—The amount of fees estab-
2 lished under subparagraph (A) shall be estab-
3 lished under subsection (d).

4 “(C) NOTICE.—

5 “(i) FISCAL YEAR 2013.—For fiscal
6 year 2013, the Secretary shall cause to be
7 published in the Federal Register a notice
8 announcing the amount of the fees pro-
9 vided for in subparagraph (A) within the
10 timeframe specified in subsection
11 (d)(1)(B).

12 “(ii) FISCAL YEARS 2014 THROUGH
13 2017.—Within the timeframe specified in
14 subsection (d)(2), the Secretary shall cause
15 to be published in the Federal Register the
16 amount of the fees under subparagraph
17 (A) for such fiscal year.

18 “(D) FREE DUE DATE.—

19 “(i) FISCAL YEAR 2013.—For fiscal
20 year 2013, the fees under subparagraph
21 (A) shall be due on the later of—

22 “(I) not later than 45 days after
23 the publication of the notice under
24 subparagraph (B); or

1 “(II) if an appropriations Act is
2 not enacted providing for the collec-
3 tion and obligation of fees under this
4 section by the date of the publication
5 of such notice, 30 days after the date
6 that such an appropriations Act is en-
7 acted.

8 “(ii) FISCAL YEARS 2014 THROUGH
9 2017.—For each of fiscal years 2014
10 through 2017, the fees under subpara-
11 graph (A) for such fiscal year shall be due
12 on the later of—

13 “(I) the first business day on or
14 after October 1 of each such year; or

15 “(II) the first business day after
16 the enactment of an appropriations
17 Act providing for the collection and
18 obligation of fees under this section
19 for such year.

20 “(5) DATE OF SUBMISSION.—For purposes of
21 this part, a generic drug submission or Type II
22 pharmaceutical master file is deemed to be ‘sub-
23 mitted’ to the Food and Drug Administration when
24 it arrives in the appropriate electronic portal of the
25 Food and Drug Administration or, if in paper form,

1 at the appropriate designated document room of the
2 Food and Drug Administration.

3 “(b) FEE REVENUE AMOUNTS.—

4 “(1) IN GENERAL.—

5 “(A) FISCAL YEAR 2013.—For fiscal year
6 2013, fees under subsection (a) shall be estab-
7 lished to generate a total estimated revenue
8 amount under such subsection of \$299,000,000.
9 Of that amount—

10 “(i) \$50,000,000 shall be generated
11 by the one-time backlog fee for generic
12 drug applications pending on October 1,
13 2012, established in subsection (a)(1); and

14 “(ii) \$249,000,000 shall be generated
15 by the fees under paragraphs (2) through
16 (4) of subsection (a).

17 “(B) FISCAL YEARS 2014 THROUGH 2017.—

18 For each of the fiscal years 2014 through 2017,
19 fees under paragraphs (2) through (4) of sub-
20 section (a) shall be established to generate a
21 total estimated revenue amount under such sub-
22 section that is equal to \$299,000,000, as ad-
23 justed pursuant to subsection (c).

24 “(2) TYPES OF FEES.—In establishing fees
25 under paragraph (1) to generate the revenue

1 amounts specified in paragraph (1)(A)(ii) for fiscal
2 year 2013 and (1)(B) for each of fiscal years 2014
3 through 2017, such fees shall be derived from the
4 fees under paragraphs (2) through (4) of subsection
5 (a) as follows:

6 “(A) 6 percent shall be derived from fees
7 under subsection (a)(2) (relating to drug mas-
8 ter files).

9 “(B) 24 percent shall be derived from fees
10 under subsection (a)(3) (relating to abbreviated
11 new drug applications and supplements). The
12 amount of a fee for a prior approval supplement
13 shall be half the amount of the fee for an ab-
14 breviated new drug application.

15 “(C) 56 percent shall be derived from fees
16 under subsection (a)(4)(A)(i) (relating to ge-
17 neric drug facilities). The amount of the fee for
18 a facility located outside the United States and
19 its territories and possessions shall be not less
20 than \$15,000 and not more than \$30,000 high-
21 er than the amount of the fee for a facility lo-
22 cated in the United States and its territories
23 and possessions, as determined by the Secretary
24 on the basis of data concerning the difference
25 in cost between inspections of facilities located

1 in the United States, including its territories
2 and possessions, and those located outside of
3 the United States and its territories and posses-
4 sions.

5 “(D) 14 percent shall be derived from fees
6 under subsection (a)(4)(A)(ii) (relating to active
7 pharmaceutical ingredient facilities). The
8 amount of the fee for a facility located outside
9 the United States and its territories and posses-
10 sions shall be not less than \$15,000 and not
11 more than \$30,000 higher than the amount of
12 the fee for a facility located in the United
13 States, including its territories and possessions,
14 as determined by the Secretary on the basis of
15 data concerning the difference in cost between
16 inspections of facilities located in the United
17 States and its territories and possessions and
18 those located outside of the United States and
19 its territories and possessions.

20 “(c) ADJUSTMENTS.—

21 “(1) INFLATION ADJUSTMENT.—For fiscal year
22 2014 and subsequent fiscal years, the revenues es-
23 tablished in subsection (b) shall be adjusted by the
24 Secretary by notice, published in the Federal Reg-

1 ister, for a fiscal year, by an amount equal to the
2 sum of—

3 “(A) one;

4 “(B) the average annual change in the
5 cost, per full-time equivalent position of the
6 Food and Drug Administration, of all personnel
7 compensation and benefits paid with respect to
8 such positions for the first 3 years of the pre-
9 ceding 4 fiscal years multiplied by the propor-
10 tion of personnel compensation and benefits
11 costs to total costs of human generic drug ac-
12 tivities for the first 3 years of the preceding 4
13 fiscal years; and

14 “(C) the average annual change that oc-
15 curred in the Consumer Price Index for urban
16 consumers (Washington-Baltimore, DC–MD–
17 VA–WV; Not Seasonally Adjusted; All items;
18 Annual Index) for the first 3 years of the pre-
19 ceding 4 years of available data multiplied by
20 the proportion of all costs other than personnel
21 compensation and benefits costs to total costs
22 of human generic drug activities for the first 3
23 years of the preceding 4 fiscal years.

24 The adjustment made each fiscal year under this
25 subsection shall be added on a compounded basis to

1 the sum of all adjustments made each fiscal year
2 after fiscal year 2013 under this subsection.

3 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
4 year 2017, the Secretary may, in addition to adjust-
5 ments under paragraph (1), further increase the fee
6 revenues and fees established in subsection (b) if
7 such an adjustment is necessary to provide for not
8 more than 3 months of operating reserves of carry-
9 over user fees for human generic drug activities for
10 the first 3 months of fiscal year 2018. Such fees
11 may only be used in fiscal year 2018. If such an ad-
12 justment is necessary, the rationale for the amount
13 of the increase shall be contained in the annual no-
14 tice establishing fee revenues and fees for fiscal year
15 2017. If the Secretary has carryover balances for
16 such activities in excess of 3 months of such oper-
17 ating reserves, the adjustment under this subpara-
18 graph shall not be made.

19 “(d) ANNUAL FEE SETTING.—

20 “(1) FISCAL YEAR 2013.—For fiscal year
21 2013—

22 “(A) the Secretary shall establish, by Octo-
23 ber 31, 2012, the one-time generic drug backlog
24 fee for generic drug applications pending on Oc-
25 tober 1, 2012, the drug master file fee, the ab-

1 breviated new drug application fee, and the
2 prior approval supplement fee under subsection
3 (a), based on the revenue amounts established
4 under subsection (b); and

5 “(B) the Secretary shall establish, not
6 later than 45 days after the date to comply
7 with the requirement for identification of facili-
8 ties in subsection (f)(2), the generic drug facil-
9 ity fee and active pharmaceutical ingredient fa-
10 cility fee under subsection (a) based on the rev-
11 enue amounts established under subsection (b).

12 “(2) FISCAL YEARS 2014 THROUGH 2017.—Not
13 more than 60 days before the first day of each of
14 fiscal years 2014 through 2017, the Secretary shall
15 establish the drug master file fee, the abbreviated
16 new drug application fee, the prior approval supple-
17 ment fee, the generic drug facility fee, and the active
18 pharmaceutical ingredient facility fee under sub-
19 section (a) for such fiscal year, based on the revenue
20 amounts established under subsection (b) and the
21 adjustments provided under subsection (c).

22 “(3) FEE FOR ACTIVE PHARMACEUTICAL IN-
23 GREDIENT INFORMATION NOT INCLUDED BY REF-
24 ERENCE TO TYPE II ACTIVE PHARMACEUTICAL IN-
25 GREDIENT DRUG MASTER FILE.—In establishing the

1 fees under paragraphs (1) and (2), the amount of
2 the fee under subsection (a)(3)(F) shall be deter-
3 mined by multiplying—

4 “(A) the sum of—

5 “(i) the total number of such active
6 pharmaceutical ingredients in such submis-
7 sion; and

8 “(ii) for each such ingredient that is
9 manufactured at more than one such facil-
10 ity, the total number of such additional fa-
11 cilities; and

12 “(B) the amount equal to the drug master
13 file fee established in subsection (a)(2) for such
14 submission.

15 “(e) LIMIT.—The total amount of fees charged, as
16 adjusted under subsection (c), for a fiscal year may not
17 exceed the total costs for such fiscal year for the resources
18 allocated for human generic drug activities.

19 “(f) IDENTIFICATION OF FACILITIES.—

20 “(1) PUBLICATION OF NOTICE; DEADLINE FOR
21 COMPLIANCE.—Not later than October 1, 2012, the
22 Secretary shall cause to be published in the Federal
23 Register a notice requiring each person that owns a
24 facility described in subsection (a)(4)(A), or a site or
25 organization required to be identified by paragraph

1 (4), to submit to the Secretary information on the
2 identity of each such facility, site, or organization.
3 The notice required by this paragraph shall specify
4 the type of information to be submitted and the
5 means and format for submission of such informa-
6 tion.

7 “(2) REQUIRED SUBMISSION OF FACILITY
8 IDENTIFICATION.—Each person that owns a facility
9 described in subsection (a)(4)(A) or a site or organi-
10 zation required to be identified by paragraph (4)
11 shall submit to the Secretary the information re-
12 quired under this subsection each year. Such infor-
13 mation shall—

14 “(A) for fiscal year 2013, be submitted not
15 later than 60 days after the publication of the
16 notice under paragraph (1); and

17 “(B) for each subsequent fiscal year, be
18 submitted, updated, or reconfirmed on or before
19 June 1 of such year.

20 “(3) CONTENTS OF NOTICE.—At a minimum,
21 the submission required by paragraph (2) shall in-
22 clude for each such facility—

23 “(A) identification of a facility identified or
24 intended to be identified in an approved or
25 pending generic drug submission;

1 “(B) whether the facility manufactures ac-
2 tive pharmaceutical ingredients or finished dos-
3 age forms, or both;

4 “(C) whether or not the facility is located
5 within the United States and its territories and
6 possessions;

7 “(D) whether the facility manufactures
8 positron emission tomography drugs solely, or
9 in addition to other drugs; and

10 “(E) whether the facility manufactures
11 drugs that are not generic drugs.

12 “(4) CERTAIN SITES AND ORGANIZATIONS.—

13 “(A) IN GENERAL.—Any person that owns
14 or operates a site or organization described in
15 subparagraph (B) shall submit to the Secretary
16 information concerning the ownership, name,
17 and address of the site or organization.

18 “(B) SITES AND ORGANIZATIONS.—A site
19 or organization is described in this subpara-
20 graph if it is identified in a generic drug sub-
21 mission and is—

22 “(i) a site in which a bioanalytical
23 study is conducted;

24 “(ii) a clinical research organization;

1 “(iii) a contract analytical testing site;

2 or

3 “(iv) a contract repackager site.

4 “(C) NOTICE.—The Secretary may, by no-
5 tice published in the Federal Register, specify
6 the means and format for submission of the in-
7 formation under subparagraph (A) and may
8 specify, as necessary for purposes of this sec-
9 tion, any additional information to be sub-
10 mitted.

11 “(D) INSPECTION AUTHORITY.—The Sec-
12 retary’s inspectional authority under section
13 704(a)(1) shall extend to all such sites and or-
14 ganizations.

15 “(g) EFFECT OF FAILURE TO PAY FEES.—

16 “(1) GENERIC DRUG BACKLOG FEE.—Failure
17 to pay the fee under subsection (a)(1) shall result in
18 the Secretary placing the person that owns the ab-
19 breviated new drug application subject to that fee on
20 an arrears list, such that no new abbreviated new
21 drug applications or supplement submitted on or
22 after October 1, 2012, from that person, or any af-
23 filiate of that person, will be received within the
24 meaning of section 505(j)(5)(A) until such out-
25 standing fee is paid.

1 “(2) DRUG MASTER FILE FEE.—

2 “(A) Failure to pay the fee under sub-
3 section (a)(2) within 20 calendar days after the
4 applicable due date under subparagraph (E) of
5 such subsection (as described in subsection
6 (a)(2)(D)(ii)(I)) shall result in the Type II ac-
7 tive pharmaceutical ingredient drug master file
8 not being deemed available for reference.

9 “(B)(i) Any generic drug submission sub-
10 mitted on or after October 1, 2012, that ref-
11 erences, by a letter of authorization, a Type II
12 active pharmaceutical ingredient drug master
13 file that has not been deemed available for ref-
14 erence shall not be received within the meaning
15 of section 505(j)(5)(A) unless the condition
16 specified in clause (ii) is met.

17 “(ii) The condition specified in this clause
18 is that the fee established under subsection
19 (a)(2) has been paid within 20 calendar days of
20 the Secretary providing the notification to the
21 sponsor of the abbreviated new drug application
22 or supplement of the failure of the owner of the
23 Type II active pharmaceutical ingredient drug
24 master file to pay the drug master file fee as
25 specified in subparagraph (C).

1 “(C)(i) If an abbreviated new drug applica-
2 tion or supplement to an abbreviated new drug
3 application references a Type II active pharma-
4 ceutical ingredient drug master file for which a
5 fee under subsection (a)(2)(A) has not been
6 paid by the applicable date under subsection
7 (a)(2)(E), the Secretary shall notify the sponsor
8 of the abbreviated new drug application or sup-
9 plement of the failure of the owner of the Type
10 II active pharmaceutical ingredient drug master
11 file to pay the applicable fee.

12 “(ii) If such fee is not paid within 20 cal-
13 endar days of the Secretary providing the noti-
14 fication, the abbreviated new drug application
15 or supplement to an abbreviated new drug ap-
16 plication shall not be received within the mean-
17 ing of 505(j)(5)(A).

18 “(3) ABBREVIATED NEW DRUG APPLICATION
19 FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—
20 Failure to pay a fee under subparagraph (A) or (F)
21 of subsection (a)(3) within 20 calendar days of the
22 applicable due date under subparagraph (C) of such
23 subsection shall result in the abbreviated new drug
24 application or the prior approval supplement to an
25 abbreviated new drug application not being received

1 within the meaning of section 505(j)(5)(A) until
2 such outstanding fee is paid.

3 “(4) GENERIC DRUG FACILITY FEE AND ACTIVE
4 PHARMACEUTICAL INGREDIENT FACILITY FEE.—

5 “(A) IN GENERAL.—Failure to pay the fee
6 under subsection (a)(4) within 20 calendar days
7 of the due date as specified in subparagraph
8 (D) of such subsection shall result in the fol-
9 lowing:

10 “(i) The Secretary shall place the fa-
11 cility on a publicly available arrears list,
12 such that no new abbreviated new drug ap-
13 plication or supplement submitted on or
14 after October 1, 2012, from the person
15 that is responsible for paying such fee, or
16 any affiliate of that person, will be received
17 within the meaning of section 505(j)(5)(A).

18 “(ii) Any new generic drug submission
19 submitted on or after October 1, 2012,
20 that references such a facility shall not be
21 received, within the meaning of
22 505(j)(5)(A) if the outstanding facility fee
23 is not paid within 20 calendar days of the
24 Secretary providing the notification to the
25 sponsor of the failure of the owner of the

1 facility to pay the facility fee under sub-
2 section (a)(4)(C).

3 “(iii) All drugs or active pharma-
4 ceutical ingredients manufactured in such
5 a facility or containing an ingredient man-
6 ufactured in such a facility shall be deemed
7 misbranded under section 502(aa).

8 “(B) APPLICATION OF PENALTIES.—The
9 penalties under this paragraph shall apply until
10 the fee established by subsection (a)(4) is paid
11 or the facility is removed from all generic drug
12 submissions that refer to the facility.

13 “(C) NONRECEIVAL FOR NONPAYMENT.—

14 “(i) NOTICE.—If an abbreviated new
15 drug application or supplement to an ab-
16 breviated new drug application submitted
17 on or after October 1, 2012, references a
18 facility for which a facility fee has not been
19 paid by the applicable date under sub-
20 section (a)(4)(C), the Secretary shall notify
21 the sponsor of the generic drug submission
22 of the failure of the owner of the facility
23 to pay the facility fee.

24 “(ii) NONRECEIVAL.—If the facility
25 fee is not paid within 20 calendar days of

1 the Secretary providing the notification
2 under clause (i), the abbreviated new drug
3 application or supplement to an abbrevi-
4 ated new drug application shall not be re-
5 ceived within the meaning of 505(j)(5)(A).

6 “(h) LIMITATIONS.—

7 “(1) IN GENERAL.—Fees under subsection (a)
8 shall be refunded for a fiscal year beginning after
9 fiscal year 2012, unless appropriations for salaries
10 and expenses of the Food and Drug Administration
11 for such fiscal year (excluding the amount of fees
12 appropriated for such fiscal year) are equal to or
13 greater than the amount of appropriations for the
14 salaries and expenses of the Food and Drug Admin-
15 istration for the fiscal year 2009 (excluding the
16 amount of fees appropriated for such fiscal year)
17 multiplied by the adjustment factor (as defined in
18 section 744A) applicable to the fiscal year involved.

19 “(2) AUTHORITY.—If the Secretary does not
20 assess fees under subsection (a) during any portion
21 of a fiscal year and if at a later date in such fiscal
22 year the Secretary may assess such fees, the Sec-
23 retary may assess and collect such fees, without any
24 modification in the rate, for Type II active pharma-
25 ceutical ingredient drug master files, abbreviated

1 new drug applications and prior approval supple-
2 ments, and generic drug facilities and active phar-
3 maceutical ingredient facilities at any time in such
4 fiscal year notwithstanding the provisions of sub-
5 section (a) relating to the date fees are to be paid.

6 “(i) CREDITING AND AVAILABILITY OF FEES.—

7 “(1) IN GENERAL.—Fees authorized under sub-
8 section (a) shall be collected and available for obliga-
9 tion only to the extent and in the amount provided
10 in advance in appropriations Acts, subject to para-
11 graph (2). Such fees are authorized to remain avail-
12 able until expended. Such sums as may be necessary
13 may be transferred from the Food and Drug Admin-
14 istration salaries and expenses appropriation account
15 without fiscal year limitation to such appropriation
16 account for salaries and expenses with such fiscal
17 year limitation. The sums transferred shall be avail-
18 able solely for human generic drug activities.

19 “(2) COLLECTIONS AND APPROPRIATION
20 ACTS.—

21 “(A) IN GENERAL.—The fees authorized
22 by this section—

23 “(i) subject to subparagraphs (C) and
24 (D), shall be collected and available in each
25 fiscal year in an amount not to exceed the

1 amount specified in appropriation Acts, or
2 otherwise made available for obligation for
3 such fiscal year; and

4 “(ii) shall be available for a fiscal year
5 beginning after fiscal year 2012 to defray
6 the costs of human generic drug activities
7 (including such costs for an additional
8 number of full-time equivalent positions in
9 the Department of Health and Human
10 Services to be engaged in such activities),
11 only if the Secretary allocates for such
12 purpose an amount for such fiscal year
13 (excluding amounts from fees collected
14 under this section) no less than
15 \$97,000,000 multiplied by the adjustment
16 factor defined in subsection (p)(3) applica-
17 ble to the fiscal year involved.

18 “(B) COMPLIANCE.—The Secretary shall
19 be considered to have met the requirements of
20 subparagraph (A)(ii) in any fiscal year if the
21 costs funded by appropriations and allocated for
22 human generic activities are not more than 10
23 percent below the level specified in such sub-
24 paragraph.

1 “(C) FEE COLLECTION DURING FIRST
2 PROGRAM YEAR.—Until the date of enactment
3 of an Act making appropriations through Sep-
4 tember 30, 2013 for the salaries and expenses
5 account of the Food and Drug Administration,
6 fees authorized by this section for fiscal year
7 2013, may be collected and shall be credited to
8 such account and remain available until ex-
9 pended.

10 “(D) PROVISION FOR EARLY PAYMENTS IN
11 SUBSEQUENT YEARS.—Payment of fees author-
12 ized under this section for a fiscal year (after
13 fiscal year 2013), prior to the due date for such
14 fees, may be accepted by the Secretary in ac-
15 cordance with authority provided in advance in
16 a prior year appropriations Act.

17 “(3) AUTHORIZATION OF APPROPRIATIONS.—
18 For each of the fiscal years 2013 through 2017,
19 there is authorized to be appropriated for fees under
20 this section an amount equivalent to the total rev-
21 enue amount determined under subsection (b) for
22 the fiscal year, as adjusted under subsection (c), if
23 applicable, or as otherwise affected under paragraph
24 (2) of this subsection.

1 “(j) COLLECTION OF UNPAID FEES.—In any case
2 where the Secretary does not receive payment of a fee as-
3 sessed under subsection (a) within 30 calendar days after
4 it is due, such fee shall be treated as a claim of the United
5 States Government subject to subchapter II of chapter 37
6 of title 31, United States Code.

7 “(k) CONSTRUCTION.—This section may not be con-
8 strued to require that the number of full-time equivalent
9 positions in the Department of Health and Human Serv-
10 ices, for officers, employees, and advisory committees not
11 engaged in human generic drug activities, be reduced to
12 offset the number of officers, employees, and advisory
13 committees so engaged.

14 “(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

15 “(1) EXEMPTION FROM FEES.—Submission of
16 an application for a positron emission tomography
17 drug or active pharmaceutical ingredient for a
18 positron emission tomography drug shall not require
19 the payment of any fee under this section. Facilities
20 that solely produce positron emission tomography
21 drugs shall not be required to pay a facility fee as
22 established in subsection (a)(4).

23 “(2) IDENTIFICATION REQUIREMENT.—Facili-
24 ties that produce positron emission tomography
25 drugs or active pharmaceutical ingredients of such

1 drugs are required to be identified pursuant to sub-
2 section (f).

3 “(m) DISPUTES CONCERNING FEES.—To qualify for
4 the return of a fee claimed to have been paid in error
5 under this section, a person shall submit to the Secretary
6 a written request justifying such return within 180 cal-
7 endar days after such fee was paid.

8 “(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—
9 An abbreviated new drug application that is not consid-
10 ered to be received within the meaning of section
11 505(j)(5)(A) because of failure to pay an applicable fee
12 under this provision within the time period specified in
13 subsection (g) shall be deemed not to have been ‘substan-
14 tially complete’ on the date of its submission within the
15 meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbrevi-
16 ated new drug application that is not substantially com-
17 plete on the date of its submission solely because of failure
18 to pay an applicable fee under the preceding sentence shall
19 be deemed substantially complete and received within the
20 meaning of section 505(j)(5)(A) as of the date such appli-
21 cable fee is received.”.

22 **SEC. 103. REAUTHORIZATION; REPORTING REQUIREMENTS.**

23 Part 7 of subchapter C of chapter VII, as added by
24 section 102 of this Act, is amended by inserting after sec-
25 tion 744B the following:

1 **“SEC. 744C. REAUTHORIZATION; REPORTING REQUIRE-**
2 **MENTS.**

3 “(a) PERFORMANCE REPORT.—Beginning with fiscal
4 year 2013, not later than 120 days after the end of each
5 fiscal year for which fees are collected under this part,
6 the Secretary shall prepare and submit to the Committee
7 on Energy and Commerce of the House of Representatives
8 and the Committee on Health, Education, Labor, and
9 Pensions of the Senate a report concerning the progress
10 of the Food and Drug Administration in achieving the
11 goals identified in the letters described in section 101(c)
12 of the Generic Drug User Fee Amendments of 2012 dur-
13 ing such fiscal year and the future plans of the Food and
14 Drug Administration for meeting the goals.

15 “(b) FISCAL REPORT.—Beginning with fiscal year
16 2013, not later than 120 days after the end of each fiscal
17 year for which fees are collected under this part, the Sec-
18 retary shall prepare and submit to the Committee on En-
19 ergy and Commerce of the House of Representatives and
20 the Committee on Health, Education, Labor, and Pen-
21 sions of the Senate a report on the implementation of the
22 authority for such fees during such fiscal year and the
23 use, by the Food and Drug Administration, of the fees
24 collected for such fiscal year.

25 “(c) PUBLIC AVAILABILITY.—The Secretary shall
26 make the reports required under subsections (a) and (b)

1 available to the public on the Internet Web site of the
2 Food and Drug Administration.

3 “(d) REAUTHORIZATION.—

4 “(1) CONSULTATION.—In developing rec-
5 ommendations to present to the Congress with re-
6 spect to the goals, and plans for meeting the goals,
7 for human generic drug activities for the first 5 fis-
8 cal years after fiscal year 2017, and for the reau-
9 thORIZATION of this part for such fiscal years, the Sec-
10 retary shall consult with—

11 “(A) the Committee on Energy and Com-
12 merce of the House of Representatives;

13 “(B) the Committee on Health, Education,
14 Labor, and Pensions of the Senate;

15 “(C) scientific and academic experts;

16 “(D) health care professionals;

17 “(E) representatives of patient and con-
18 sumer advocacy groups; and

19 “(F) the generic drug industry.

20 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
21 negotiations with the generic drug industry on the
22 reauthorization of this part, the Secretary shall—

23 “(A) publish a notice in the Federal Reg-
24 ister requesting public input on the reauthoriza-
25 tion;

1 “(B) hold a public meeting at which the
2 public may present its views on the reauthoriza-
3 tion, including specific suggestions for changes
4 to the goals referred to in subsection (a);

5 “(C) provide a period of 30 days after the
6 public meeting to obtain written comments from
7 the public suggesting changes to this part; and

8 “(D) publish the comments on the Food
9 and Drug Administration’s Internet Web site.

10 “(3) PERIODIC CONSULTATION.—Not less fre-
11 quently than once every month during negotiations
12 with the generic drug industry, the Secretary shall
13 hold discussions with representatives of patient and
14 consumer advocacy groups to continue discussions of
15 their views on the reauthorization and their sugges-
16 tions for changes to this part as expressed under
17 paragraph (2).

18 “(4) PUBLIC REVIEW OF RECOMMENDA-
19 TIONS.—After negotiations with the generic drug in-
20 dustry, the Secretary shall—

21 “(A) present the recommendations devel-
22 oped under paragraph (1) to the Congressional
23 committees specified in such paragraph;

24 “(B) publish such recommendations in the
25 Federal Register;

1 “(C) provide for a period of 30 days for
2 the public to provide written comments on such
3 recommendations;

4 “(D) hold a meeting at which the public
5 may present its views on such recommenda-
6 tions; and

7 “(E) after consideration of such public
8 views and comments, revise such recommenda-
9 tions as necessary.

10 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
11 Not later than January 15, 2017, the Secretary
12 shall transmit to the Congress the revised rec-
13 ommendations under paragraph (4), a summary of
14 the views and comments received under such para-
15 graph, and any changes made to the recommenda-
16 tions in response to such views and comments.

17 “(6) MINUTES OF NEGOTIATION MEETINGS.—

18 “(A) PUBLIC AVAILABILITY.—Before pre-
19 senting the recommendations developed under
20 paragraphs (1) through (5) to the Congress, the
21 Secretary shall make publicly available, on the
22 public Web site of the Food and Drug Adminis-
23 tration, minutes of all negotiation meetings con-
24 ducted under this subsection between the Food

1 and Drug Administration and the generic drug
2 industry.

3 “(B) CONTENT.—The minutes described
4 under subparagraph (A) shall summarize any
5 substantive proposal made by any party to the
6 negotiations as well as significant controversies
7 or differences of opinion during the negotiations
8 and their resolution.”.

9 **SEC. 104. SUNSET DATES.**

10 (a) AUTHORIZATION.—The amendments made by
11 section 102 cease to be effective October 1, 2017.

12 (b) REPORTING REQUIREMENTS.—The amendments
13 made by section 103 cease to be effective January 31,
14 2018.

15 **SEC. 105. EFFECTIVE DATE.**

16 The amendments made by this title shall take effect
17 on October 1, 2012, or the date of the enactment of this
18 title, whichever is later, except that fees under section 102
19 shall be assessed for all human generic drug submissions
20 and Type II active pharmaceutical drug master files re-
21 ceived on or after October 1, 2012, regardless of the date
22 of enactment of this title.

1 **SEC. 106. AMENDMENT WITH RESPECT TO MISBRANDING.**

2 Section 502 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 352) is amended by adding at the end the
4 following:

5 “(aa) If it is a drug, or an active pharmaceutical in-
6 gredient, and it was manufactured, prepared, propagated,
7 compounded, or processed in a facility for which fees have
8 not been paid as required by section 744A(a)(4) or for
9 which identifying information required by section 744B(f)
10 has not been submitted, or it contains an active pharma-
11 ceutical ingredient that was manufactured, prepared,
12 propagated, compounded, or processed in such a facility.”.

13 **SEC. 107. ELECTRONIC SUBMISSION OF APPLICATIONS.**

14 The Federal Food, Drug, and Cosmetic Act is amend-
15 ed by inserting after section 745 the following:

16 **“SEC. 745A. ELECTRONIC SUBMISSION OF APPLICATIONS:.**

17 “(a) IN GENERAL.—Beginning no earlier than 24
18 months after the issuance of a final guidance issued after
19 public notice and opportunity for comment, submissions
20 under section 505(j) shall be submitted in such electronic
21 format as specified by the Secretary in such guidance.

22 “(b) GUIDANCE CONTENTS.—In such guidance, the
23 Secretary may provide a timetable for establishment by
24 the Secretary of further standards for such electronic sub-
25 mission, and set forth criteria for waivers of and exemp-
26 tions from the requirements of this section.

1 “(c) EXCEPTION.—This section shall not apply to
2 submissions described in section 561.”.

3 **SEC. 108. STREAMLINED HIRING AUTHORITY OF THE FOOD**
4 **AND DRUG ADMINISTRATION TO SUPPORT**
5 **ACTIVITIES RELATED TO HUMAN GENERIC**
6 **DRUGS.**

7 Subchapter A of chapter VII of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-
9 ed by inserting after section 713 the following new section:
10 **“SEC. 714. STREAMLINED HIRING AUTHORITY.**

11 “(a) IN GENERAL.—In addition to any other per-
12 sonnel authorities under other provisions of law, the Sec-
13 retary may, without regard to the provisions of title 5,
14 United States Code, governing appointments in the com-
15 petitive service, appoint employees to positions in the Food
16 and Drug Administration to perform, administer, or sup-
17 port activities described in subsection (b), if the Secretary
18 determines that such appointments are needed to achieve
19 the objectives specified in subsection (c).

20 “(b) ACTIVITIES DESCRIBED.—The activities de-
21 scribed in this subsection are activities under this Act re-
22 lated to human generic drug activities (as defined in sec-
23 tion 744A).

24 “(c) OBJECTIVES SPECIFIED.—The objectives speci-
25 fied in this subsection are the performance goals with re-

1 spect to section 744A (regarding assessment and use of
2 human generic drug fees), as set forth in the letters de-
3 scribed in section 101(c) of the Generic Drug User Fee
4 Amendments of 2012.

5 “(d) INTERNAL CONTROLS.—The Secretary shall in-
6 stitute appropriate internal controls for appointments
7 under this section.

8 “(e) SUNSET.—The authority to appoint employees
9 under this section shall terminate on the date that is three
10 years after the date of enactment of this section.”.

11 **TITLE II—FEES RELATING TO**
12 **BIOSIMILAR BIOLOGICAL**
13 **PRODUCTS**

14 **SEC. 201. SHORT TITLE; REFERENCES IN TITLE; FINDING.**

15 (a) SHORT TITLE.—This title may be cited as the
16 “Biosimilar User Fee Act of 2012”.

17 (b) REFERENCES IN ACT.—Except as otherwise spec-
18 ified, amendments made by this title to a section or other
19 provision of law are amendments to such section or other
20 provision of the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 301 et seq.).

22 (c) FINDING.—The Congress finds that the fees au-
23 thorized by the amendments made in this title will be dedi-
24 cated to expediting the process for the review of biosimilar
25 biological product applications, including postmarket safe-

1 ty activities, as set forth in the goals identified for pur-
2 poses of part 8 of subchapter C of chapter VII of the Fed-
3 eral Food, Drug, and Cosmetic Act, in the letters from
4 the Secretary of Health and Human Services to the Chair-
5 man of the Committee on Health, Education, Labor, and
6 Pensions of the Senate and the Chairman of the Com-
7 mittee on Energy and Commerce of the House of Rep-
8 resentatives, as set forth in the Congressional Record.

9 **SEC. 202. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
10 **PRODUCTS.**

11 Subchapter C of chapter VII (21 U.S.C. 379f et seq.)
12 is amended by inserting after part 7, as added by title
13 I of this Act, the following:

14 **“PART 8—FEES RELATING TO BIOSIMILAR**
15 **BIOLOGICAL PRODUCTS**

16 **“SEC. 744G. DEFINITIONS.**

17 “For purposes of this part:

18 “(1) The term ‘adjustment factor’ applicable to
19 a fiscal year that is the Consumer Price Index for
20 all urban consumers (Washington-Baltimore, DC–
21 MD–VA–WV; Not Seasonally Adjusted; All items) of
22 the preceding fiscal year divided by such Index for
23 September 2011.

1 “(2) The term ‘affiliate’ means a business enti-
2 ty that has a relationship with a second business en-
3 tity if, directly or indirectly—

4 “(A) one business entity controls, or has
5 the power to control, the other business entity;
6 or

7 “(B) a third party controls, or has power
8 to control, both of the business entities.

9 “(3) The term ‘biosimilar biological product’
10 means a product for which a biosimilar biological
11 product application has been approved.

12 “(4)(A) Subject to subparagraph (B), the term
13 ‘biosimilar biological product application’ means an
14 application for licensure of a biological product
15 under section 351(k) of the Public Health Service
16 Act.

17 “(B) Such term does not include—

18 “(i) a supplement to such an application;

19 “(ii) an application filed under section
20 351(k) of the Public Health Service Act that
21 cites as the reference product a bovine blood
22 product for topical application licensed before
23 September 1, 1992, or a large volume paren-
24 teral drug product approved before such date;

1 “(iii) an application filed under section
2 351(k) of the Public Health Service Act with
3 respect to—

4 “(I) whole blood or a blood component
5 for transfusion;

6 “(II) an allergenic extract product;

7 “(III) an in vitro diagnostic biological
8 product; or

9 “(IV) a biological product for further
10 manufacturing use only; or

11 “(iv) an application for licensure under
12 section 351(k) of the Public Health Service Act
13 that is submitted by a State or Federal Govern-
14 ment entity for a product that is not distributed
15 commercially.

16 “(5) The term ‘biosimilar biological product de-
17 velopment meeting’ means any meeting, other than
18 a biosimilar initial advisory meeting, regarding the
19 content of a development program, including a pro-
20 posed design for, or data from, a study intended to
21 support a biosimilar biological product application.

22 “(6) The term ‘biosimilar biological product de-
23 velopment program’ means the program under this
24 part for expediting the process for the review of sub-

1 missions in connection with biosimilar biological
2 product development.

3 “(7)(A) The term ‘biosimilar biological product
4 establishment’ means a foreign or domestic place of
5 business—

6 “(i) that is at one general physical location
7 consisting of one or more buildings, all of which
8 are within five miles of each other; and

9 “(ii) at which one or more biosimilar bio-
10 logical products are manufactured in final dos-
11 age form.

12 “(B) For purposes of subparagraph (A)(ii), the
13 term ‘manufactured’ does not include packaging.

14 “(8) The term ‘biosimilar initial advisory meet-
15 ing’—

16 “(A) means a meeting, if requested, that is
17 limited to—

18 “(i) a general discussion regarding
19 whether licensure under section 351(k) of
20 the Public Health Service Act may be fea-
21 sible for a particular product; and

22 “(ii) if so, general advice on the ex-
23 pected content of the development pro-
24 gram; and

1 “(B) does not include any meeting that in-
2 volves substantive review of summary data or
3 full study reports.

4 “(9) The term ‘costs of resources allocated for
5 the process for the review of biosimilar biological
6 product applications’ means the expenses in connec-
7 tion with the process for the review of biosimilar bio-
8 logical product applications for—

9 “(A) officers and employees of the Food
10 and Drug Administration, contractors of the
11 Food and Drug Administration, advisory com-
12 mittees, and costs related to such officers em-
13 ployees and committees and to contracts with
14 such contractors;

15 “(B) management of information, and the
16 acquisition, maintenance, and repair of com-
17 puter resources;

18 “(C) leasing, maintenance, renovation, and
19 repair of facilities and acquisition, maintenance,
20 and repair of fixtures, furniture, scientific
21 equipment, and other necessary materials and
22 supplies; and

23 “(D) collecting fees under section 744H
24 and accounting for resources allocated for the
25 review of submissions in connection with bio-

1 similar biological product development, bio-
2 similar biological product applications, and sup-
3 plements.

4 “(10) The term ‘final dosage form’ means, with
5 respect to a biosimilar biological product, a finished
6 dosage form which is approved for administration to
7 a patient without substantial further manufacturing
8 (such as lyophilized products before reconstitution).

9 “(11) The term ‘financial hold’—

10 “(A) means an order issued by the Sec-
11 retary to prohibit the sponsor of a clinical in-
12 vestigation from continuing the investigation if
13 the Secretary determines that the investigation
14 is intended to support a biosimilar biological
15 product application and the sponsor has failed
16 to pay any fee for the product required under
17 subparagraph (A), (B), or (D) of section
18 744H(a)(1); and

19 “(B) does not mean that any of the bases
20 for a ‘clinical hold’ under section 505(i)(3) have
21 been determined by the Secretary to exist con-
22 cerning the investigation.

23 “(12) The term ‘person’ includes an affiliate of
24 such person.

1 “(13) The term ‘process for the review of bio-
2 similar biological product applications’ means the
3 following activities of the Secretary with respect to
4 the review of submissions in connection with bio-
5 similar biological product development, biosimilar bi-
6 ological product applications, and supplements:

7 “(A) The activities necessary for the re-
8 view of submissions in connection with bio-
9 similar biological product development, bio-
10 similar biological product applications, and sup-
11 plements.

12 “(B) Actions related to submissions in con-
13 nection with biosimilar biological product devel-
14 opment, the issuance of action letters which ap-
15 prove biosimilar biological product applications
16 or which set forth in detail the specific defi-
17 ciencies in such applications, and where appro-
18 priate, the actions necessary to place such ap-
19 plications in condition for approval.

20 “(C) The inspection of biosimilar biological
21 product establishments and other facilities un-
22 dertaken as part of the Secretary’s review of
23 pending biosimilar biological product applica-
24 tions and supplements.

1 “(D) Activities necessary for the release of
2 lots of biosimilar biological products under sec-
3 tion 351(k) of the Public Health Service Act.

4 “(E) Monitoring of research conducted in
5 connection with the review of biosimilar biologi-
6 cal product applications.

7 “(F) Postmarket safety activities with re-
8 spect to biologics approved under biosimilar bio-
9 logical product applications or supplements, in-
10 cluding the following activities:

11 “(i) Collecting, developing, and re-
12 viewing safety information on biosimilar bi-
13 ological products, including adverse event
14 reports.

15 “(ii) Developing and using improved
16 adverse-event data-collection systems, in-
17 cluding information technology systems.

18 “(iii) Developing and using improved
19 analytical tools to assess potential safety
20 problems, including access to external data
21 bases.

22 “(iv) Implementing and enforcing sec-
23 tion 505(o) (relating to postapproval stud-
24 ies and clinical trials and labeling changes)

1 and section 505(p) (relating to risk evalua-
2 tion and mitigation strategies).

3 “(v) Carrying out section 505(k)(5)
4 (relating to adverse event reports and
5 postmarket safety activities).

6 “(14) The term ‘supplement’ means a request
7 to the Secretary to approve a change in a biosimilar
8 biological product application which has been ap-
9 proved, including a supplement requesting that the
10 Secretary determine that the biosimilar biological
11 product meets the standards for interchangeability
12 described in section 351(k)(4) of the Public Health
13 Service Act.

14 **“SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
15 **BIOLOGICAL PRODUCT FEES.**

16 “(a) TYPES OF FEES.—Beginning in fiscal year
17 2013, the Secretary shall assess and collect fees in accord-
18 ance with this section as follows:

19 “(1) BIOSIMILAR DEVELOPMENT PROGRAM
20 FEES.—

21 “(A) INITIAL BIOSIMILAR BIOLOGICAL
22 PRODUCT DEVELOPMENT FEE.—

23 “(i) IN GENERAL.—Each person that
24 submits to the Secretary a meeting request
25 described under clause (ii) or a clinical

1 protocol for an investigational new drug
2 protocol described under clause (iii) shall
3 pay for the product named in the meeting
4 request or the investigational new drug ap-
5 plication the initial biosimilar biological
6 product development fee established under
7 subsection (b)(1)(A).

8 “(ii) MEETING REQUEST.—The meet-
9 ing request defined in this clause is a re-
10 quest for a biosimilar biological product
11 development meeting for a product.

12 “(iii) CLINICAL PROTOCOL FOR IND.—
13 A clinical protocol for an investigational
14 new drug protocol described in this clause
15 is a clinical protocol consistent with the
16 provisions of section 505(i), including any
17 regulations promulgated under section
18 505(i), (referred to in this section as ‘in-
19 vestigational new drug application’) de-
20 scribing an investigation that the Secretary
21 determines is intended to support a bio-
22 similar biological product application for a
23 product.

1 “(iv) DUE DATE.—The initial bio-
2 similar biological product development fee
3 shall be due by the earlier of the following:

4 “(I) Not later than 5 days after
5 the Secretary grants a request for a
6 biosimilar biological product develop-
7 ment meeting.

8 “(II) The date of submission of
9 an investigational new drug applica-
10 tion describing an investigation that
11 the Secretary determines is intended
12 to support a biosimilar biological
13 product application.

14 “(v) TRANSITION RULE.—Each per-
15 son that has submitted an investigational
16 new drug application prior to the date of
17 enactment of the Biosimilars User Fee Act
18 of 2012 shall pay the initial biosimilar bio-
19 logical product development fee by the ear-
20 lier of the following:

21 “(I) Not later than 60 days after
22 the date of the enactment of the
23 Biosimilars User Fee Act of 2012, if
24 the Secretary determines that the in-
25 vestigational new drug application de-

1 scribes an investigation that is in-
2 tended to support a biosimilar biologi-
3 cal product application.

4 “(II) Not later than 5 days after
5 the Secretary grants a request for a
6 biosimilar biological product develop-
7 ment meeting.

8 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
9 PRODUCT DEVELOPMENT FEE.—

10 “(i) IN GENERAL.—A person that
11 pays an initial biosimilar biological product
12 development fee for a product shall pay for
13 such product, beginning in the fiscal year
14 following the fiscal year in which the initial
15 biosimilar biological product development
16 fee was paid, an annual fee established
17 under subsection (b)(1)(B) for biosimilar
18 biological product development (referred to
19 in this section as ‘annual biosimilar bio-
20 logical product development fee’).

21 “(ii) DUE DATE.—The annual bio-
22 similar biological product development pro-
23 gram fee for each fiscal year will be due on
24 the later of—

1 “(I) the first business day on or
2 after October 1 of each such year; or

3 “(II) the first business day after
4 the enactment of an appropriations
5 Act providing for the collection and
6 obligation of fees for such year under
7 this section.

8 “(iii) EXCEPTION.—The annual bio-
9 similar development program fee for each
10 fiscal year will be due on the date specified
11 in clause (ii), unless the person has—

12 “(I) submitted a marketing appli-
13 cation for the biological product that
14 was accepted for filing; or

15 “(II) discontinued participation
16 in the biosimilar biological product de-
17 velopment program for the product
18 under subparagraph (C).

19 “(C) DISCONTINUATION OF FEE OBLIGA-
20 TION.—A person may discontinue participation
21 in the biosimilar biological product development
22 program for a product effective October 1 of a
23 fiscal year by, not later than August 1 of the
24 preceding fiscal year—

1 “(i) if no investigational new drug ap-
2 plication concerning the product has been
3 submitted, submitting to the Secretary a
4 written declaration that the person has no
5 present intention of further developing the
6 product as a biosimilar biological product;
7 or

8 “(ii) if an investigational new drug
9 application concerning the product has
10 been submitted, by withdrawing the inves-
11 tigational new drug application in accord-
12 ance with part 312 of title 21, Code of
13 Federal Regulations (or any successor reg-
14 ulations).

15 “(D) REACTIVATION FEE.—

16 “(i) IN GENERAL.—A person that has
17 discontinued participation in the biosimilar
18 biological product development program for
19 a product under subparagraph (C) shall
20 pay a fee (referred to in this section as ‘re-
21 activation fee’) by the earlier of the fol-
22 lowing:

23 “(I) Not later than 5 days after
24 the Secretary grants a request for a
25 biosimilar biological product develop-

1 ment meeting for the product (after
2 the date on which such participation
3 was discontinued).

4 “(II) Upon the date of submis-
5 sion (after the date on which such
6 participation was discontinued) of an
7 investigational new drug application
8 describing an investigation that the
9 Secretary determines is intended to
10 support a biosimilar biological product
11 application for that product.

12 “(ii) APPLICATION OF ANNUAL
13 FEE.—A person that pays a reactivation
14 fee for a product shall pay for such prod-
15 uct, beginning in the next fiscal year, the
16 annual biosimilar biological product devel-
17 opment fee under subparagraph (B).

18 “(E) EFFECT OF FAILURE TO PAY BIO-
19 SIMILAR DEVELOPMENT PROGRAM FEES.—

20 “(i) NO BIOSIMILAR BIOLOGICAL
21 PRODUCT DEVELOPMENT MEETINGS.—If a
22 person has failed to pay an initial or an-
23 nual biosimilar biological product develop-
24 ment fee as required under subparagraph
25 (A) or (B), or a reactivation fee as re-

1 required under subparagraph (D), the Sec-
2 retary shall not provide a biosimilar bio-
3 logical product development meeting relat-
4 ing to the product for which fees are owed.

5 “(ii) NO RECEIPT OF INVESTIGA-
6 TIONAL NEW DRUG APPLICATIONS.—Ex-
7 cept in extraordinary circumstances, the
8 Secretary shall not consider an investiga-
9 tional new drug application to have been
10 received under section 505(i)(2) if—

11 “(I) the Secretary determines
12 that the investigation is intended to
13 support a biosimilar biological product
14 application; and

15 “(II) the sponsor has failed to
16 pay an initial or annual biosimilar bio-
17 logical product development fee for
18 the product as required under sub-
19 paragraph (A) or (B), or a reactiva-
20 tion fee as required under subpara-
21 graph (D).

22 “(iii) FINANCIAL HOLD.—Notwith-
23 standing section 505(i)(2), except in ex-
24 traordinary circumstances, the Secretary
25 shall prohibit the sponsor of a clinical in-

1 vestigation from continuing the investiga-
2 tion if—

3 “(I) the Secretary determines
4 that the investigation is intended to
5 support a biosimilar biological product
6 application; and

7 “(II) the sponsor has failed to
8 pay an initial or annual biosimilar bio-
9 logical product development fee for
10 the product as required under sub-
11 paragraph (A) or (B), or a reactiva-
12 tion fee for the product as required
13 under subparagraph (D).

14 “(iv) NO ACCEPTANCE OF BIOSIMILAR
15 BIOLOGICAL PRODUCT APPLICATIONS OR
16 SUPPLEMENTS.—If a person has failed to
17 pay an initial or annual biosimilar biologi-
18 cal product development fee as required
19 under subparagraph (A) or (B), or a reac-
20 tivation fee as required under subpara-
21 graph (D), any biosimilar biological prod-
22 uct application or supplement submitted by
23 that person shall be considered incomplete
24 and shall not be accepted for filing by the

1 Secretary until all such fees owed by such
2 person have been paid.

3 “(F) LIMITS REGARDING BIOSIMILAR DE-
4 VELOPMENT PROGRAM FEES.—

5 “(i) NO REFUNDS.—The Secretary
6 shall not refund any initial or annual bio-
7 similar biological product development fee
8 paid under subparagraph (A) or (B), or
9 any reactivation fee paid under subpara-
10 graph (D).

11 “(ii) NO WAIVERS, EXEMPTIONS, OR
12 REDUCTIONS.—The Secretary shall not
13 grant a waiver, exemption, or reduction of
14 any initial or annual biosimilar biological
15 product development fee due or payable
16 under subparagraph (A) or (B), or any re-
17 activation fee due or payable under sub-
18 paragraph (D).

19 “(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
20 CATION AND SUPPLEMENT FEE.—

21 “(A) IN GENERAL.—Each person that sub-
22 mits, on or after October 1, 2012, a biosimilar
23 biological product application or a supplement
24 shall be subject to the following fees:

1 “(i) A fee for a biosimilar biological
2 product application that is equal to—

3 “(I) the amount of the fee estab-
4 lished under subsection (b)(1)(D) for
5 a biosimilar biological product applica-
6 tion; minus

7 “(II) the cumulative amount of
8 fees paid, if any, under subparagraphs
9 (A), (B), and (D) of paragraph (1)
10 for the product that is the subject of
11 the application.

12 “(ii) A fee for a biosimilar biological
13 product application for which clinical data
14 (other than comparative bioavailability
15 studies) with respect to safety or effective-
16 ness are not required, that is equal to—

17 “(I) half of the amount of the fee
18 established under subsection (b)(1)(D)
19 for a biosimilar biological product ap-
20 plication; minus

21 “(II) the cumulative amount of
22 fees paid, if any, under subparagraphs
23 (A), (B), and (D) of paragraph (1)
24 for that product.

1 “(iii) A fee for a supplement for which
2 clinical data (other than comparative bio-
3 availability studies) with respect to safety
4 or effectiveness are required, that is equal
5 to half of the amount of the fee established
6 under subsection (b)(1)(D) for a biosimilar
7 biological product application.

8 “(B) REDUCTION IN FEES.—Notwith-
9 standing section 204 of the Biosimilars User
10 Fee Act of 2012, any person who pays a fee
11 under subparagraph (A), (B), or (D) of para-
12 graph (1) for a product before October 1, 2017,
13 but submits a biosimilar biological product ap-
14 plication for that product after such date, shall
15 be entitled to the reduction of any biosimilar bi-
16 ological product application fees that may be
17 assessed at the time when such biosimilar bio-
18 logical product application is submitted, by the
19 cumulative amount of fees paid under subpara-
20 graphs (A), (B), and (D) of paragraph (1) for
21 that product.

22 “(C) PAYMENT DUE DATE.—Any fee re-
23 quired by subparagraph (A) shall be due upon
24 submission of the application or supplement for
25 which such fee applies.

1 “(D) EXCEPTION FOR PREVIOUSLY FILED
2 APPLICATION OR SUPPLEMENT.—If a biosimilar
3 biological product application or supplement
4 was submitted by a person that paid the fee for
5 such application or supplement, was accepted
6 for filing, and was not approved or was with-
7 drawn (without a waiver), the submission of a
8 biosimilar biological product application or a
9 supplement for the same product by the same
10 person (or the person’s licensee, assignee, or
11 successor) shall not be subject to a fee under
12 subparagraph (A).

13 “(E) REFUND OF APPLICATION FEE IF AP-
14 PLICATION REFUSED FOR FILING OR WITH-
15 DRAWN BEFORE FILING.—The Secretary shall
16 refund 75 percent of the fee paid under this
17 paragraph for any application or supplement
18 which is refused for filing or withdrawn without
19 a waiver before filing.

20 “(F) FEES FOR APPLICATIONS PRE-
21 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
22 BEFORE FILING.—A biosimilar biological prod-
23 uct application or supplement that was sub-
24 mitted but was refused for filing, or was with-
25 drawn before being accepted or refused for fil-

1 ing, shall be subject to the full fee under sub-
2 paragraph (A) upon being resubmitted or filed
3 over protest, unless the fee is waived under sub-
4 section (c).

5 “(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTAB-
6 LISHMENT FEE.—

7 “(A) IN GENERAL.—Except as provided in
8 subparagraph (E)(ii), each person that is
9 named as the applicant in a biosimilar biologi-
10 cal product application shall be assessed an an-
11 nual fee established under subsection (b)(1)(E)
12 for each biosimilar biological product establish-
13 ment that is listed in the approved biosimilar
14 biological product application as an establish-
15 ment that manufactures the biosimilar biologi-
16 cal product named in such application.

17 “(B) ASSESSMENT IN FISCAL YEARS.—The
18 establishment fee shall be assessed in each fis-
19 cal year for which the biosimilar biological prod-
20 uct named in the application is assessed a fee
21 under paragraph (4) unless the biosimilar bio-
22 logical product establishment listed in the appli-
23 cation does not engage in the manufacture of
24 the biosimilar biological product during such
25 fiscal year.

1 “(C) DUE DATE.—The establishment fee
2 for a fiscal year shall be due on the later of—

3 “(i) the first business day on or after
4 October 1 of such fiscal year; or

5 “(ii) the first business day after the
6 enactment of an appropriations Act pro-
7 viding for the collection and obligation of
8 fees for such fiscal year under this section.

9 “(D) APPLICATION TO ESTABLISHMENT.—

10 “(i) Each biosimilar biological product
11 establishment shall be assessed only one
12 fee per biosimilar biological product estab-
13 lishment, notwithstanding the number of
14 biosimilar biological products manufac-
15 tured at the establishment, subject to
16 clause (ii).

17 “(ii) In the event an establishment is
18 listed in a biosimilar biological product ap-
19 plication by more than one applicant, the
20 establishment fee for the fiscal year shall
21 be divided equally and assessed among the
22 applicants whose biosimilar biological prod-
23 ucts are manufactured by the establish-
24 ment during the fiscal year and assessed

1 biosimilar biological product fees under
2 paragraph (4).

3 “(E) EXCEPTION FOR NEW PRODUCTS.—

4 If, during the fiscal year, an applicant initiates
5 or causes to be initiated the manufacture of a
6 biosimilar biological product at an establish-
7 ment listed in its biosimilar biological product
8 application—

9 “(i) that did not manufacture the bio-
10 similar biological product in the previous
11 fiscal year; and

12 “(ii) for which the full biosimilar bio-
13 logical product establishment fee has been
14 assessed in the fiscal year at a time before
15 manufacture of the biosimilar biological
16 product was begun,

17 the applicant shall not be assessed a share of
18 the biosimilar biological product establishment
19 fee for the fiscal year in which the manufacture
20 of the product began.

21 “(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

22 “(A) IN GENERAL.—Each person who is
23 named as the applicant in a biosimilar biologi-
24 cal product application shall pay for each such

1 biosimilar biological product the annual fee es-
2 tablished under subsection (b)(1)(F).

3 “(B) DUE DATE.—The biosimilar biologi-
4 cal product fee for a fiscal year shall be due on
5 the later of—

6 “(i) the first business day on or after
7 October 1 of each such year; or

8 “(ii) the first business day after the
9 enactment of an appropriations Act pro-
10 viding for the collection and obligation of
11 fees for such year under this section.

12 “(C) ONE FEE PER PRODUCT PER YEAR.—
13 The biosimilar biological product fee shall be
14 paid only once for each product for each fiscal
15 year.

16 “(b) FEE SETTING AND AMOUNTS.—

17 “(1) IN GENERAL.—Subject to paragraph (2),
18 the Secretary shall, 60 days before the start of each
19 fiscal year that begins after September 30, 2012, es-
20 tablish, for the next fiscal year, the fees under sub-
21 section (a). Except as provided in subsection (c),
22 such fees shall be in the following amounts:

23 “(A) INITIAL BIOSIMILAR BIOLOGICAL
24 PRODUCT DEVELOPMENT FEE.—The initial bio-
25 similar biological product development fee under

1 subsection (a)(1)(A) for a fiscal year shall be
2 equal to 10 percent of the amount established
3 under section 736(c)(5) for a human drug ap-
4 plication described in section 736(a)(1)(A)(i)
5 for that fiscal year.

6 “(B) ANNUAL BIOSIMILAR BIOLOGICAL
7 PRODUCT DEVELOPMENT FEE.—The annual
8 biosimilar biological product development fee
9 under subsection (a)(1)(B) for a fiscal year
10 shall be equal to 10 percent of the amount es-
11 tablished under section 736(c)(5) for a human
12 drug application described in section
13 736(a)(1)(A)(i) for that fiscal year.

14 “(C) REACTIVATION FEE.—The reactiva-
15 tion fee under subsection (a)(1)(D) for a fiscal
16 year shall be equal to 20 percent of the amount
17 of the fee established under section 736(c)(5)
18 for a human drug application described in sec-
19 tion 736(a)(1)(A)(i) for that fiscal year.

20 “(D) BIOSIMILAR BIOLOGICAL PRODUCT
21 APPLICATION FEE.—The biosimilar biological
22 product application fee under subsection (a)(2)
23 for a fiscal year shall be equal to the amount
24 established under section 736(c)(5) for a

1 human drug application described in section
2 736(a)(1)(A)(i) for that fiscal year.

3 “(E) BIOSIMILAR BIOLOGICAL PRODUCT
4 ESTABLISHMENT FEE.—The biosimilar biological
5 product establishment fee under subsection
6 (a)(3) for a fiscal year shall be equal to the
7 amount established under section 736(c)(5) for
8 a prescription drug establishment for that fiscal
9 year.

10 “(F) BIOSIMILAR BIOLOGICAL PRODUCT
11 FEE.—The biosimilar biological product fee
12 under subsection (a)(4) for a fiscal year shall be
13 equal to the amount established under section
14 736(c)(5) for a prescription drug product for
15 that fiscal year.

16 “(2) LIMIT.—The total amount of fees charged
17 for a fiscal year under this section may not exceed
18 the total amount for such fiscal year of the costs of
19 resources allocated for the process for the review of
20 biosimilar biological product applications.

21 “(c) APPLICATION FEE WAIVER FOR SMALL BUSI-
22 NESS.—

23 “(1) WAIVER OF APPLICATION FEE.—The Sec-
24 retary shall grant to a person who is named in a bio-
25 similar biological product application a waiver from

1 the application fee assessed to that person under
2 subsection (a)(2)(A) for the first biosimilar biological
3 product application that a small business or its
4 affiliate submits to the Secretary for review. After a
5 small business or its affiliate is granted such a waiver,
6 the small business or its affiliate shall pay—

7 “(A) application fees for all subsequent
8 biosimilar biological product applications sub-
9 mitted to the Secretary for review in the same
10 manner as an entity that is not a small busi-
11 ness; and

12 “(B) all supplement fees for all supple-
13 ments to biosimilar biological product applica-
14 tions submitted to the Secretary for review in
15 the same manner as an entity that is not a
16 small business.

17 “(2) CONSIDERATIONS.—In determining wheth-
18 er to grant a waiver of a fee under paragraph (1),
19 the Secretary shall consider only the circumstances
20 and assets of the applicant involved and any affiliate
21 of the applicant.

22 “(3) SMALL BUSINESS DEFINED.—In this sub-
23 section, the term ‘small business’ means an entity
24 that has fewer than 500 employees, including em-
25 ployees of affiliates, and does not have a drug prod-

1 uct that has been approved under a human drug ap-
2 plication (as defined in section 735) or a biosimilar
3 biological product application (as defined in section
4 744G(4)) and introduced or delivered for introduc-
5 tion into interstate commerce.

6 “(d) EFFECT OF FAILURE TO PAY FEES.—A bio-
7 similar biological product application or supplement sub-
8 mitted by a person subject to fees under subsection (a)
9 shall be considered incomplete and shall not be accepted
10 for filing by the Secretary until all fees owed by such per-
11 son have been paid.

12 “(e) CREDITING AND AVAILABILITY OF FEES.—

13 “(1) IN GENERAL.—Subject to paragraph (2),
14 fees authorized under subsection (a) shall be col-
15 lected and available for obligation only to the extent
16 and in the amount provided in advance in appropria-
17 tions Acts. Such fees are authorized to remain avail-
18 able until expended. Such sums as may be necessary
19 may be transferred from the Food and Drug Admin-
20 istration salaries and expenses appropriation account
21 without fiscal year limitation to such appropriation
22 account for salaries and expenses with such fiscal
23 year limitation. The sums transferred shall be avail-
24 able solely for the process for the review of bio-
25 similar biological product applications.

1 “(2) COLLECTIONS AND APPROPRIATION
2 ACTS.—

3 “(A) IN GENERAL.—Subject to subpara-
4 graphs (C) and (D), the fees authorized by this
5 section shall be collected and available in each
6 fiscal year in an amount not to exceed the
7 amount specified in appropriation Acts, or oth-
8 erwise made available for obligation for such
9 fiscal year.

10 “(B) USE OF FEES AND LIMITATION.—
11 The fees authorized by this section shall be
12 available for a fiscal year beginning after fiscal
13 year 2012 to defray the costs of the process for
14 the review of biosimilar biological product appli-
15 cations (including such costs for an additional
16 number of full-time equivalent positions in the
17 Department of Health and Human Services to
18 be engaged in such process), only if the Sec-
19 retary allocates for such purpose an amount for
20 such fiscal year (excluding amounts from fees
21 collected under this section) no less than
22 \$20,000,000, multiplied by the adjustment fac-
23 tor applicable to the fiscal year involved.

24 “(C) FEE COLLECTION DURING FIRST
25 PROGRAM YEAR.—Until the date of enactment

1 of an Act making appropriations through Sep-
2 tember 30, 2013, for the salaries and expenses
3 account of the Food and Drug Administration,
4 fees authorized by this section for fiscal year
5 2013 may be collected and shall be credited to
6 such account and remain available until ex-
7 pended.

8 “(D) PROVISION FOR EARLY PAYMENTS IN
9 SUBSEQUENT YEARS.—Payment of fees author-
10 ized under this section for a fiscal year (after
11 fiscal year 2013), prior to the due date for such
12 fees, may be accepted by the Secretary in ac-
13 cordance with authority provided in advance in
14 a prior year appropriations Act.

15 “(3) AUTHORIZATION OF APPROPRIATIONS.—
16 For each of fiscal years 2013 through 2017, there
17 is authorized to be appropriated for fees under this
18 section an amount equivalent to the total amount of
19 fees assessed for such fiscal year under this section.

20 “(f) COLLECTION OF UNPAID FEES.—In any case
21 where the Secretary does not receive payment of a fee as-
22 sessed under subsection (a) within 30 days after it is due,
23 such fee shall be treated as a claim of the United States
24 Government subject to subchapter II of chapter 37 of title
25 31, United States Code.

1 “(g) WRITTEN REQUESTS FOR WAIVERS AND RE-
2 FUNDS.—To qualify for consideration for a waiver under
3 subsection (c), or for a refund of any fee collected in ac-
4 cordance with subsection (a)(2)(A), a person shall submit
5 to the Secretary a written request for such waiver or re-
6 fund not later than 180 days after such fee is due.

7 “(h) CONSTRUCTION.—This section may not be con-
8 strued to require that the number of full-time equivalent
9 positions in the Department of Health and Human Serv-
10 ices, for officers, employers, and advisory committees not
11 engaged in the process of the review of biosimilar biologi-
12 cal product applications, be reduced to offset the number
13 of officers, employees, and advisory committees so en-
14 gaged.”.

15 **SEC. 203. REAUTHORIZATION; REPORTING REQUIREMENTS.**

16 Part 8 of subchapter C of chapter VII, as amended
17 by section 202 of this Act, is further amended by inserting
18 after section 744H the following:

19 **“SEC. 744I. REAUTHORIZATION; REPORTING REQUIRE-**
20 **MENTS.**

21 “(a) PERFORMANCE REPORT.—Beginning with fiscal
22 year 2013, not later than 120 days after the end of each
23 fiscal year for which fees are collected under this part,
24 the Secretary shall prepare and submit to the Committee
25 on Energy and Commerce of the House of Representatives

1 and the Committee on Health, Education, Labor, and
2 Pensions of the Senate a report concerning the progress
3 of the Food and Drug Administration in achieving the
4 goals identified in the letters described in section 201(c)
5 of the Biosimilars User Fee Act of 2012 during such fiscal
6 year and the future plans of the Food and Drug Adminis-
7 tration for meeting such goals. The report for a fiscal year
8 shall include information on all previous cohorts for which
9 the Secretary has not given a complete response on all
10 biosimilar biological product applications and supplements
11 in the cohort.

12 “(b) FISCAL REPORT.—Not later than 120 days after
13 the end of fiscal year 2013 and each subsequent fiscal year
14 for which fees are collected under this part, the Secretary
15 shall prepare and submit to the Committee on Energy and
16 Commerce of the House of Representatives and the Com-
17 mittee on Health, Education, Labor, and Pensions of the
18 Senate a report on the implementation of the authority
19 for such fees during such fiscal year and the use, by the
20 Food and Drug Administration, of the fees collected for
21 such fiscal year.

22 “(c) PUBLIC AVAILABILITY.—The Secretary shall
23 make the reports required under subsections (a) and (b)
24 available to the public on the Internet Web site of the
25 Food and Drug Administration.

1 “(d) STUDY.—

2 “(1) IN GENERAL.—The Secretary shall con-
3 tract with an independent accounting or consulting
4 firm to study the workload volume and full costs as-
5 sociated with the process for the review of biosimilar
6 biological product applications.

7 “(2) INTERIM RESULTS.—Not later than June
8 1, 2015, the Secretary shall publish, for public com-
9 ment, interim results of the study described under
10 paragraph (1).

11 “(3) FINAL RESULTS.—Not later than Sep-
12 tember 30, 2016, the Secretary shall publish, for
13 public comment, the final results of the study de-
14 scribed under paragraph (1).

15 “(e) REAUTHORIZATION.—

16 “(1) CONSULTATION.—In developing rec-
17 ommendations to present to the Congress with re-
18 spect to the goals described in subsection (a), and
19 plans for meeting the goals, for the process for the
20 review of biosimilar biological product applications
21 for the first 5 fiscal years after fiscal year 2017, and
22 for the reauthorization of this part for such fiscal
23 years, the Secretary shall consult with—

24 “(A) the Committee on Energy and Com-
25 merce of the House of Representatives;

1 “(B) the Committee on Health, Education,
2 Labor, and Pensions of the Senate;

3 “(C) scientific and academic experts;

4 “(D) health care professionals;

5 “(E) representatives of patient and con-
6 sumer advocacy groups; and

7 “(F) the regulated industry.

8 “(2) PUBLIC REVIEW OF RECOMMENDA-
9 TIONS.—After negotiations with the regulated indus-
10 try, the Secretary shall—

11 “(A) present the recommendations devel-
12 oped under paragraph (1) to the Congressional
13 committees specified in such paragraph;

14 “(B) publish such recommendations in the
15 Federal Register;

16 “(C) provide for a period of 30 days for
17 the public to provide written comments on such
18 recommendations;

19 “(D) hold a meeting at which the public
20 may present its views on such recommenda-
21 tions; and

22 “(E) after consideration of such public
23 views and comments, revise such recommenda-
24 tions as necessary.

1 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
2 Not later than January 15, 2017, the Secretary
3 shall transmit to the Congress the revised rec-
4 ommendations under paragraph (2), a summary of
5 the views and comments received under such para-
6 graph, and any changes made to the recommenda-
7 tions in response to such views and comments.”.

8 **SEC. 204. SUNSET DATES.**

9 (a) AUTHORIZATION.—The amendment made by sec-
10 tion 202 shall cease to be effective October 1, 2017.

11 (b) REPORTING REQUIREMENTS.—The amendment
12 made by section 203 shall cease to be effective January
13 31, 2018.

14 **SEC. 205. EFFECTIVE DATE.**

15 (a) IN GENERAL.—Except as provided under sub-
16 section (b), the amendments made by this title shall take
17 effect on the later of—

18 (1) October 1, 2012; or

19 (2) the date of the enactment of this title.

20 (b) EXCEPTION.—Fees under part 7 of subchapter
21 C of chapter VII of the Federal Food, Drug, and Cosmetic
22 Act, as added by this title, shall be assessed for all bio-
23 similar biological product applications received on or after
24 October 1, 2012, regardless of the date of the enactment
25 of this title.

1 **SEC. 206. SAVINGS CLAUSE.**

2 Notwithstanding section 106 of the Prescription
3 Drug User Fee Amendments of 2007 (21 U.S.C. 379g
4 note), and notwithstanding the amendments made by this
5 title, part 2 of subchapter C of chapter VII of the Federal
6 Food, Drug, and Cosmetic Act, as in effect on the day
7 before the date of the enactment of this title, shall con-
8 tinue to be in effect with respect to human drug applica-
9 tions and supplements (as defined in such part as of such
10 day) that were accepted by the Food and Drug Adminis-
11 tration for filing on or after October 1, 2007, but before
12 October 1, 2012, with respect to assessing and collecting
13 any fee required by such part for a fiscal year prior to
14 fiscal year 2013.

15 **SEC. 207. TECHNICAL AMENDMENT; CONFORMING AMEND-**
16 **MENT.**

17 Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amend-
18 ed by striking “or (k)”.

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